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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/047,257	01/15/2002	Myung-Sam Cho	MSB-7255.2	4520
7590	12/18/2003			
Christine M. Hansen Connolly Bove Lodge & Hutz LLP 1220 Market Street P.O. Box 2207 Wilmington, DE 19899				
			EXAMINER ROBINSON, HOPE A	
			ART UNIT 1653	PAPER NUMBER
DATE MAILED: 12/18/2003				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/047,257	CHO ET AL.	
	Examiner	Art Unit	
	Hope A. Robinson	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 January 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 1-18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

1. The Preliminary amendment filed January 15, 2002 has been received and entered. It is noted that applicant canceled claim 19.

Claim Disposition

2. Claim 19 has been canceled. Claims 1-18 are pending and under examination.

Specification

3. The disclosure is objected to because of the following informalities:

The specification is objected to because trademarks are disclosed and they are not capitalized. The use of the trademark such as Humulin®, Coatest® etc., has been noted in this application (see pages 6 and 27 for example). It should be capitalized wherever it appears and be accompanied by the generic terminology. Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner, which might adversely affect their validity as trademarks. The specification is also objected to because page 1 of the application refers to application numbers MSB-7241 and MSB -7254, instead of 10/047,257 and 10/006,091.

Correction is required.

Priority

4. It is noted that applicant has claimed priority under 35 U.S.C. 120 and/or 121 (domestic), however, the information needs to be updated as the continuation application 09/209,916 is now U.S. Patent No. 6,358,703.

Basis For Statutory Double Patenting

5. A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

6. Claims 1-18 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of Claims 1-18 of copending Application No. 10/006,091. Claims 1-18 in the instant application and Claims 1-18 in the copending application have the same language, scope,

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wording and subject matter. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

Basis For NonStatutory Double Patenting

7. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

8. Claims 1, 5, 7, 11-12, 14, 16 and 18 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claims 1, 2 and 6 of U.S. Patent

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No. 6,358,703. Although the conflicting claims are not identical, they are not patentably distinct from each other because the patented claims are an obvious variation of the instant claims. The patented claims are directed to a method of producing and isolating a protein having factor VIII activity comprising growing cells designated as ATCC CRL-12568 which include a sequence coding for the protein operably linked to a promoter, the growing takes place under conditions sufficient to express the protein. The patented claims are also directed to a protein contained in SEQ ID NO: 1 and a human cell line which expresses a protein having factor VIII activity. The instant claims are directed to the production of a cell expressing the factor VIII having procoagulant activity solely of a human origin. The steps outlined in the method of claim 1 of the instant application are practiced in the patent as the claims directed to first growing cells expressing factor VIII activity. In addition, the patented claims and instant claims use the same cells, ATCC CRL-12568 and have the identical protein set forth in SEQ ID NO: 1. Therefore, the instant claims are an extension of the patented claims.

Claim Rejections - 35 USC § 112

9. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-18 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one

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skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claimed invention is directed to a method of producing cells and which are hybrids of 2B8 and HKB11 (ATCC CRL-12569 and ATCC CRL-12568, respectively). Page 5 of the specification refers to deposits made at ATCC, however, the specification does not provide information such as whether the deposit was made under the Budapest Treaty and the date and address of the depository (ATCC) is not disclosed.

Therefore, it is not known essential information pertaining to the claimed invention is known and publicly available or can be reproducibly isolated. Without publicly available deposit information one of skill in the art could not be assured of the ability to practice the invention as claimed.

Applicant's referral to the deposit made to ATCC on page 5 of the specification is noted but is considered insufficient assurance that all of the conditions of 37 CFR 1.801-1.809 have been met. If deposits have not been made under the Budapest Treaty, then in order to certify that the deposits meet the criteria set forth in 37 CFR 1.801-1.809, applicant may provide assurance of compliance by an affidavit or declaration, or by a statement by an attorney of record over his or her signature and registration number, showing that:

(A) During the pendency of this application, access to the invention will be afforded to the Commissioner upon request;

(B) All restrictions upon availability to the public will be irrevocably removed upon granting of the patent;

(C) The deposits will be maintained in a public depository for a period of 30 years or 5 years after the last request or for the effective life of the patent, whichever is longer;

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(D) The deposits were viable at the time of deposit;

(E) The deposits will be replaced if they should ever become non-viable.

This requirement is necessary when a deposit is made under the provisions of the Budapest Treaty as the Treaty leaves these specific matters to the discretion of each member State. Amendment of the specification to disclose the date of the deposit and the complete name and address of the depository is required.

For further information concerning deposit practice, applicants attention is directed to In re Lundak 773 F 2d 1216 227 USPQ CAFC and 37 CFR 1.801-1.809.

10. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 and the dependent claims hereto are indefinite because the claim recites in the preamble "a protein having factor VIII procoagulant activity" and step (d) of the method recites "the protein having factor VIII activity". It is not apparent if the same activity in the preamble is sought or achieved in step (d).

Claim 14 is indefinite for the recitation of "(SEQ ID NO:1)" as the notation should be (SEQ ID NO:1).

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Claim 13 is indefinite because the claim does not further limit claim 11 which depends from claim 1 and recites that the cells are "solely of human origin".

Claims 15 and 17 are indefinite for the recitation of the relative term "high levels" because the term is not defined in the claim. It is noted that a discussion is provided on page 3 of the specification which does not breathe life into the claim and the limitations of the specification cannot be read into the claims. Therefore a standard for ascertaining the requisite amount or the amount needs to be recited in the claim.

Claims 15-18 are indefinite for the recitation of "derived from" as the specification indicates that "as used herein to described the origin of cell lines, derived from is intended to include but not limited to normal mitotic cell division and processes such as transfections, cell fusions, or other genetic engineering techniques used to alter cells or produce cells with new properties (see page 3)". Therefore, it is suggested that applicant delete the term "derived from" and replace it with "obtained from".

Claims 16 and 18 are indefinite because the claim lacks antecedent basis as the claim from which it depends does not "a cell line".

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

- (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are

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such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103 (a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103 (c) and potential 35 U.S.C. 102 (f) or (g) prior art under 35 U.S.C. 103 (a).

12. Claim 1 is rejected under 35 U.S.C. 103 (a) as being unpatentable over Chan (U.S. Patent No. 5,952,198, April 17, 1996).

Chan teach mammalian cells expressing factor VIII under serum free conditions.

Although the reference does not teach the sequential steps set forth in claim 1 the fact that they produced a cell that expresses an increased amount of factor VIII suggests that the steps found in claim 1 were practiced as the steps are routine in the art. As factor VIII is expressed in the cells, the procoagulant activity would be expected because this is a property of factor VIII. Chan also teach expression in 293S cells (human embryonic kidney cells) which meets the claimed limitation of "solely human origin". Chan also teach cells expressing BDD-FVIII, the determination of the factor VIII activity using Coatest VIII and the use of GS-MDR (see abstract and columns 1-3).

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Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to develop a method to produce cells expressing a protein having factor VIII procoagulant activity using the steps set forth in claim 1 with a reasonable expectation of success because the method steps recited in the claim are routine in the art and Chan teaches cells that were produced to express an increased amount of factor VIII, thus, the steps recited in the claim would have been practiced by Chan. In addition, the invention as claimed is within the skill of the art, because on page 5 of the specification it is stated that "similar vectors can be constructed and used by those having skill in the art to obtain cells expressing proteins having factor VIII procoagulant activity. For example, coding sequences coding for known variants of factor VIII which retain procoagulant activity can be substituted for the BDD-FVIII coding sequence. Also, instead of dhfr, other selectable markers can be used, such as glutamine synthetase (gs) or multidrug-resistance gene (mdr). The choice of a selection agent must be made accordingly, as is known in the art....". Thus, the claimed invention is within the skill of the art and *prima facie* obvious.

Conclusion

13. No claims are allowable.


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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Hope Robinson whose telephone number is (703) 308-6231. The examiner can normally be reached on Monday-Friday from 7.00 am to 3.30 pm (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached at (703) 308-1152.

Any inquiries of a general nature relating to this application should be directed to the Group Receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted by facsimile transmission. The official fax phone number for Technology Center 1600 is (703) 308-4242. Please affix the examiner's name on a cover sheet attached to your communication should you choose to fax your response. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG (November 15, 1989).

Hope Robinson, MS 

Patent Examiner


CHRISTOPHER S. F. LOW
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600